

## REMARKS

### Pending Claims

Claims 1-17 and 19-51 are pending. Claim 18 is canceled by way of this response. Claims 1, 20, and 37 are amended. Claims 1 and 20 are amended to recite that the calibrator or control remains stable when stored at temperatures of from about 2 to about 8°C for a period of about twelve (12) months or more. This amendment is fully supported by the specification as originally filed, e.g., at page 11, lines 25-28. Claim 37 is amended to recite that the diluent and natriuretic peptide are mixed together at a temperature of from about 15°C to about 30°C until a homogenous solution is obtained. This amendment is fully supported by the specification as originally filed, e.g., at page 12, lines 24-26.

### Double Patenting Rejection

The pending claims have been amended to overcome the provisional double patenting requirement. Applicants will file a terminal disclaimer in the second allowed case if the allowed claims of the second application are not patentably distinct from the allowed claims of the first granted application.

### Anticipation/Obviousness Rejection

The instant rejection is identical to that in copending U.S. Patent Application No. 10/721,031. Applicants responses are also identical.

The Office Action alleges that claims 1 - 51 are not patentable under sections 102 and 103 over Burnett et al. (U.S. Patent 6,407,211). The Office Action acknowledges that Burnett et al. fails to teach the pH limitations of the independent claims of the subject application. The Office Action argues, however, that a natriuretic peptide, a buffer, an acid, and a base would inherently exhibit a pH value with the pH ranges claimed in the present invention. The rejection is respectfully traversed.

An invention is not anticipated or obvious over the prior if the prior art does not disclose each and every limitation of the claim. There is nothing in the disclosure of Burnett et al. to suggest a solution of natriuretic peptide having a pH of 4.0 - 6.5, and the Office Action does not provide any evidence to the contrary.

The Office Action also alleges that applicants bear the burden to show patentably distinct differences of the claimed invention to the prior art reference. This is incorrect. The

burden of proof shifts to applicants after a *prima facie* showing of anticipation or obviousness has been made. A *prima facie* showing requires that the Office identify prior art disclosing each and every claim limitation. However, here the Office Action admits that the prior art fails to teach or reasonably suggest the pH limitation. Accordingly, the burden of proof remains on the Patent Office. It is also proper to shift the burden to the applicants where the applicants assert that the claimed invention differs from the prior art in that a parameter of the product is said to differ from that of the prior art when both products are made by identical processes. The processes involved here, however, cannot be shown to be identical at least because the prior art does not disclose the pH of any buffer used.

Finally, the Office asserts that the pH of the prior art solutions is *inherently* the same as those of the claimed invention. This assertion cannot be supported. An invention is not inherently anticipated by a prior art disclosure unless the teachings of the prior art always and inevitably produces the claimed invention. Again, however, there is nothing in Burnett et al. to explicitly teach or reasonably suggest a pH of 4.0 - 6.5 in a relevant solution.


For the foregoing reasons, the subject application is believed to be in good form for allowance. The Examiner is therefore requested to pass this application to issue. If, in the opinion of the Examiner, a telephonic interview would expedite the prosecution of the present application, the Examiner is invited to contact applicants' undersigned attorney.

Conclusion

The application is believed to be in condition for allowance. The Examiner is respectfully requested to pass this application to allowance. If in the opinion of the Examiner, a telephonic interview would expedite the prosecution of the subject patent application, the Examiner is invited to contact the undersigned attorney.

Respectfully submitted,

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